Patent Appl. No. 10/647,919
Docket No. 15634 (PC25246)
Filing Date: August 26, 2003

REMARKS

I. Preliminary Remarks

The Claims were subject to a Restriction Requirement, mailed March 9, 2006. Applicant chose Group I, Claims 1-11, 20-31 and 76-83, drawn to an immunogenic/vaccine composition, and elected the species of *Leptospira borgpetersenii hardjo-bovis*.

The Office issued a final office action on December 21. 2006. Applicants filed a response on March 21, 2007. The Office then issued an Advisory Action on April 30, 2007 in which the Examiner stated that the proposed amendments were entered, the request for reconsideration had been considered but did NOT place the application in condition for allowance, and an explanation of how the new or amended claims would be rejected was appended. This Request for Continued Examination (RCE) is filed in response to the Advisory Action.

After entry of this paper, Claims 3 and 22 are original. Claims 1-2, 4-5, 7-11, 20-21, 23, 25, 27-31, 76-77, and 79-82 are previously presented. Claims 12-19, and 32-75 are withdrawn. Claims 6, 24, 26, 78, and 83 are canceled. Withdrawn and canceled claims are withdrawn without prejudice in an effort to favorably advance prosecution of the present application. Applicant reserves the right to pursue the subject matter of the withdrawn or canceled claims in a continuation application, or to have the withdrawn claims rejoined in the current application.

In this response, Applicant addresses each of the rejections raised by the Examiner. Reconsideration and withdrawal of the rejections are solicited for the reasons set out below. Applicant respectfully submits that the present application is in condition for allowance. Favorable consideration of all pending claims is respectfully requested.

This Response is filed with a petition for revival of the application under 37 CFR 1.137(b). The USPTO is given authorization to charge Deposit Account No. 16-1445 for any fees necessary with the submission of this Response.

II. Patentability Arguments

A. The anticipation rejection of Claims 1-2, 7-11, 20-21, 27-31, 76, and 80-82 under 35 U.S.C. §102(b) may properly be withdrawn.

A patent is invalid for anticipation under 35 USC 102(b) if a single prior art reference identically discloses each and every limitation of the invention as set forth in the claims. (Lewmar Marine, Inc. v. Barient, Inc., 827 F.2d 744, 747 (Fed. Cir. 1987)). The prior publication must disclose in an enabling manner the invention that is in question. The exclusion of a claimed element, no matter how insubstantial or obvious, from a reference is enough to negate anticipation. (Connell v. Sears, Roebuck & Co., 220 U.S.P.Q. 193, 1098 (Fed. Cir. 1983)). Applicant respectfully submits that these criteria are not met in the Examiner's rejection. The claims, therefore, are not anticipated by the references.

The Examiner has maintained the rejection of claims 1-2, 7-11, 20-21, 27-31, 76, and 80-82 under 35 U.S.C. 102(b) as being anticipated by Bowland, et al., (Canadian Veterinary Journal, Jan 2000, Vol. 41, No. 1, pages 33-48). Applicants respectfully traverse the rejection.

As stated above, a rejection of a claim for anticipation requires that the single cited reference disclose each and every element of the claim in an enabling manner. Bowland, et al., do not anticipate the claimed invention because they fail to disclose each and every element of the claim in an enabling manner. There is nothing in Bowland, et al., that enables an immunogenic composition or a vaccine composition comprising two different strains (Types 1 and 2) of BVD virus. They merely reference BoviShield™3 in Table 1 (Line 21, Page 35) and indicate that it contains BVDV. Bowland, et al., do not teach that BoviShield™3 contains both BVDV Types 1 and 2. The Examiner would need to refer to another reference to determine whether both Types are included in BoviShield™3. However, this is not the standard for an anticipation rejection.

Thus, Bowland, et al., do not teach each and every limitation of independent Claims 1, 20, or 76 of the instant application. The other rejected claims either depend from one of these independent claims or from a claim that depends from them. These dependent claims further delineate the independent claims; they embody all the elements of them. Accordingly, the subject matter of the dependent claims is not anticipated by Bowland.

Thus, based on the remarks presented herein, the rejection of claims 1-2, 7-11, 20-21, 27-31, 76, and 80-82 under 35 U.S.C. 102(b) is overcome. Withdrawal of the rejection is therefore respectfully requested.

B. The Obviousness Rejection of Claims 1-11, 20-31, 76-83 under 35 U.S.C. §103(a) May Be Properly Withdrawn.

As stated in the MPEP (§2141), to support an obviousness rejection, four basic criteria must be met. These are (A) The claimed invention must be considered as a whole; (B) The references must be considered as a whole and must suggest the desirability and thus the obviousness of making the combination; (C) The references must be viewed without the benefit of impermissible hindsight vision afforded by the claimed invention; and (D) Reasonable expectation of success is the standard with which obviousness is determined. Clearly for prior art to render an invention obvious, it must render obvious the whole invention and not merely some part of the invention (*In re Antonie* 559 F.2d 618, 620, 195 USPQ 6,8 (CCPA 1997)). The prior art must also be considered as a whole including parts that teach away from Applicant's invention. Applicant respectfully submits that these criteria are not met in the Examiner's rejections.

The Examiner has maintained the rejection of claims 1-11, 20-31, 76-79, and 80-83 under 35 U.S.C. 103(a) as being unpatentable under Bowland, et al., as applied to claims 1-2, 7-11, 20-21, 27-31, 76, and 80-82 above, and further in view of Barr, et al., (Advanced Drug Delivery Reviews, 1998, Vol. 32, No. 3, pages 247-271), Pruett, et al., (Veterinary Parasitology, 1995, Vol. 58, No. 1-2, pages 143-153), and Wilson, et al., (Canadian Journal of Veterinary Research, Oct 1995, Vol. 59, No. 4, pages 299-305). Applicants respectfully traverse this rejection.

The arguments presented section IIA above also apply to this section. That is, Bowland do not teach a vaccine comprising BVDV Types 1 and 2. As indicated by the sub-heading within Table 1 of Bowland, et al., (Line 21, Page 35) BoviShield™3 is categorized as a 3-Way MLV vaccine, thus containing 3 viral antigens: strains of IBR, BVD, and PI_3 viruses. Bowland do not indicate whether the BVDV is Type 1, Type 2, or both. The description of the antigenic composition of BoviShield™3 previously provided by Applicants (Compendium of Veterinary Products, Eighth Edition, published January 2005) states that "BoviShield™3 is a freeze-dried preparation of modified live virus (MLV) strains of IBR, BVD, and PI_3 viruses." However, while the brochure states the vaccine offers protection against BVDV Types 1 and 2, there is no information about the type of BVDV

antigen present in it. This reference does not state whether the preparation contains BVDV Type 1, Type 2, or both. Also the viral antigens contained in BoviShield™3 are only IBRV, PI3 and BVDV. It does not contain all of the viral antigens contained in the compositions of the present invention, which include BHV-1, PI3, BRSV, BVDV-1, and BVDV-2 (see Claims 1, 20, and 76 of the instant application).

In the sub-heading within Table 1 of Bowland, et al., (Line 21, Page 35), BoviShield™3 is categorized as a 3-Way MLV vaccine, The term MLV stands for "Modified Live Virus" as opposed to inactivated virus. While BoviShield™3 is a composition containing a modified live BVD viral antigen, Claims 2, 21, 80, and 82 of the instant invention are drawn to antigen compositions comprising two different inactivated strains (Types 1 and 2) of BVD virus. Thus, Bowland, et al., do not anticipate these claims of the instant invention.

The terms "inactivated" vaccines and "modified live virus" vaccines are described in the specification (see paragraphs 0008 and 0009). In addition, one skilled in the art would understand the difference between an MLV vaccine and an inactivated vaccine. These terms have been used in the art for many years. The Examiner is referred to the dates of the references provided in the specification. For inactivated virus vaccines, references were published in 1972, 1978, 1995, and 2000. For MLV vaccines, references were published in 1961, 1975, 1984, and 1986.

When the arguments provided in the responses to the prior office actions of May 1, 2006 and December 21, 2006 combined with the arguments presented in this current response the rejection is overcome. In summary, Bowland, et al., do not teach the antigen compositions of the present invention. The antigen composition claimed in the present invention is a mixture of two BVD viral antigens whereas Bowland, et al., do not specify the type of BVD viral antigen. See discussion above.

As established in our prior responses, and further in combination with the present response, a person skilled in the art could not combine the Bowland reference with the teachings about adjuvants in the Barr et al., Pruett et al., or Wilson, et al., references to reach a composition of the present invention because they do not teach or suggest the adjuvant compositions of the present invention.

The present invention claims an adjuvant composition comprising an oil-in-water emulsion (such as Amphigen) and Quil A (a saponin). Barr, et al., teaches in general about the chemistry and the mode of action of saponin adjuvants. This reference also teaches the preparation and use of immunostimulatory complexes (ISCOM) based on saponin adjuvant. While it teaches the use of Quil A in combination with liposomes, microspheres, and aluminum salts, there is neither a teaching nor a suggestion for combining Quil A with an oil-in-water emulsion such as Amphigen.

Pruett, et al., teach a combination of Amphigen and alhydrogel as an adjuvant in a vaccine formulation comprising hypodermin A protein as an antigen. There is no teaching in this reference for combining Quil A with Amphigen. Moreover, this reference focused on showing a synergy in the antibody response due to this Amphigen-Alhydrogel combination. A person skilled in making viral vaccines would have paid attention towards selecting an adjuvant combination based on the synergy in terms of cellular immune response, as the cellular immune response is more important in offering protective immune response due to vaccination. Pruett, et al., suggest the mixture of alhydrogel and amphigen to be worthy of further efficacy investigation in a vaccine formulation only with hypodermin A. There is nothing in Pruett to suggest that the adjuvants used in the cattle grub hypodermin A homogenate vaccine could be used successfully in the compositions of the present invention. Thus a person skilled in the art would not have combined the teachings of Pruett, et al., to prepare a vaccine of present invention.

Wilson, et al., teach the use of a variety of adjuvants in testing the subunit vaccines prepared from extracts of Actinobacillus pleuropnemoniae. Included in the list of adjuvants tested in this study are Amphigen and Quil A. However, in this reference there was no suggestion to combine Amphigen with Quil A. In one of the animal trials in this study (Trial III, Page 303) Amphigen was used either alone or in combination with vitamin E. As the results shown in the Table III on page 303 indicates, combining Vitamin E with Amphigen significantly reduced the adjuvanticity of Amphigen. With the addition of Vitamin E to Amphigen, the protective immune response, measured in terms of antibody titer, decreased while the mortality rate increased. At the same time addition of Vitamin E to Canola improved the protective immune response. Thus a person skilled in the art, upon seeing the

results of Wilson, et al., would be resistant to combine any other adjuvant component with Amphigen in a vaccine formulation.

The Applicant respectfully submits that none of the references cited by the Examiner suggest Applicant's invention. There is no indication in any of the references that would suggest that the references be combined. Moreover, even when combined the references do not yield Applicant's invention. Accordingly, it is respectfully submitted that the immunogenic compositions and vaccine compositions, as presently claimed, are not rendered obvious by Bowland, et al., in view of Barr, et al., Pruett, et al., and Wilson, et al. Thus, based on the remarks presented herein, the rejection of claims 1-11,20-31, 76-79, and 80-83 under 35 U.S.C. 103(a) as being unpatentable under Bowland, et al., as applied to claims 1-2, 7-11, 20-21, 27-31, 76, and 80-82 is overcome. Withdrawal of the rejection is respectfully requested.

III. Conclusion.

In view of the remarks made herein, Applicants respectfully submit that Claims 1-5, 7-11, 20-23, 25, 27-31, 76-77, and 79-82 are in condition for allowance and request notification of same.

Respectfully submitted,

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